510 (K) Summary of Safety and Effectiveness

MAR 1 6 2012

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

Submitter:

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Contact person:

Yue Qiuhong
Edan Instruments, Inc.

Date:

2011-12-01

Proprietary Name:

SE-1201

Classification Name:

21 CFR 870.2340 Electrocardiograph
Class II

Product code:

DPS

Predicate Devices:

MAC 5000 ECG Analysis System K014108
Manufacturer: GE medical systems information technologies

Device Description:

SE-1201 is 12-channel electrocardiograph, it's configured with a 7inch Multi-color screen with 800*480 dots resolution.
SE-1201 is mainly composed of the ECG board, the power supply board, the Key board and the main board.
SE-1201 can acquire 12 channel waveforms simultaneously, which can also print out 12 channel electrocardiograph wave simultaneously by a 216mm wide thermal printer, and the waveforms also can be displayed in LCD and stored in flash memory or send to PC by Ethernet.
SE-1201 has the features as follows:
Supporting barcode scanner
Supporting multi-language

ECG signals of 12 leads are gathered and amplified simultaneously, 12-channel waves are displayed and recorded simultaneously
Full alphanumeric keyboard (touch screen is optional)
Real-time uploading to PC ECG
Multiple file formats: DAT, PDF, SCP, FDA-XML
High resolution thermal recorder, recording frequency response ≤150Hz
Flexible printing formats
The auto, manual, rhythm, R-R analysis and off modes can be chosen freely
Automatic baseline adjustment for optimal printing
Convenient operation of system setup and file management
Measurement function and interpretation function
Hint information of lead off, lack of paper, low battery capacity etc.
Built-in rechargeable lithium battery with large capacity
ECG data can be transmitted to the PC software through the net cable, or wireless AP (optional).

Intended Use: The intended use of SE-1201 12-channel electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.

Test Summary: The following quality assurance measures were applied to the development of the SE-1201.

- Software testing
- Risk analysis
- Safety testing
- Environment testing

Conclusion: Verification and validation testing was done on SE-1201. This pre-market notification submission demonstrates that SE-1201 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 16 2012

Edan Instruments
c/o Ms. Tracy Yue
Certification Engineer
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Shenzhen
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CHINA

Re: K120188
Trade/Device Name: SE-1201
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: February 17, 2012
Received: February 21, 2012

Dear Ms. Yue:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: SE-1201

The intended use of SE-1201 12-channel electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.

Prescription Use ___X___ Or Over the Counter Use _____

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120188